IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	Confirmation No.: 2424
Shiping WANG et al.	Art Unit: 1615
Application No.: 10/783,362	Examiner: Hasan S. Ahmed
Filed: February 20, 2004	Attorney Dkt. No.: 029714-00017
For: ANTIMICROBIAL MEDICAL GLOVES	

DECLARATION OF NICHOLAS R. KROGMAN, Ph.D.
UNDER 37 C.F.R. § 1.132

I, Nicholas R. Krogman, Ph.D., hereby declare and affirm that:

1. My curriculum vitae, including a list of my publications and credentials, is attached as Exhibit A.

2. The present application is assigned to Allegiance Corporation. Allegiance Corporation is wholly owned by Cardinal Health. I am a Senior Research Scientist in the Cardinal Health Research and Development Department. I do not have any financial interest in U.S. Patent Application No. 10/783,362.

3. I have reviewed the disclosure of U.S. Patent Application No. 10/783,362, the currently-pending claims, the Office Action mailed on September 2, 2011 in this application, and the prior art references cited therein. I understand that the Office Action has taken the position that the currently-pending claims are obvious in view of the combined disclosures of U.S. Patent No. 5,133,090 ("Modak"), U.S. Application No. 2002/0152538 ("McDevitt"), U.S. Patent No. 5,322,161 ("Shichman"), and U.S. Patent No. 5,357,636 ("Dresdner"). More specifically, I have conducted testing to demonstrate that a person of ordinary skill in the art, having the disclosures of these references before him, would not have been able to combine their teachings to arrive at the inventions set forth in claims 27-29, 33-34, and 50-52.

4. Independent claim 27 relates to a packaged antimicrobial elastomeric article. The packaged antimicrobial elastomeric article includes:

an elastomeric article that is essentially free of powder and starch, and is coated with at least one wetting agent, at least one antifoaming agent, and at least one antimicrobial agent; and

a package enclosing said elastomeric article and comprising a desiccant for reducing the relative humidity in the vicinity of the elastomeric article to less than the ambient relative humidity;

wherein the packaged elastomeric article is capable of causing at least 1 $\log_{10}$ reduction of the initial number of microorganisms that come into contact with the treated glove surface in five minutes of contact after being stored and/or transported for at least 45 days.

5. Claims 28-29, 33-34, and 50-52 each depend directly or indirectly from claim 27.

6. The Modak reference describes an antiviral surgical or examination glove including a biguanide anti-infective agent and a lubricating agent/donning aid. The examples set forth in Modak involve coating a glove with a slurry containing a non-adsorbent lubricating agent, and an antiviral agent.

7. The Dresdner reference describes medical gloves that include a non-liquid antiseptic composition provided between inner and outer elastomeric layers of a glove, so that the antiseptic composition can protect the hand of the wearer from infections if the glove is punctured.

8. The McDevitt reference describes a finger glove formed from a nonwoven web material that is liquid impermeable, but vapor permeable. The finger glove may be contained in a package, where the packaging materials can include ethylene vinyl alcohol (EVA) film, film foil laminates, metalized films, multi-layered plastic films.

9. The Shichman reference describes packages containing desiccants for preserving bioabsorbable articles, such as surgical staples and clips, and instruments that contain such articles. The packaging materials can include laminate films including a polymeric base layer, an intermediate inorganic thin film layer, and a heat sealable coating layer. The desiccants can include crystalline aluminosilicates (such as zeolite Z-12) and silica gels.

10. In the September 2, 2011 Office Action, the Modak, Dresdner, McDevitt and Schichman references were combined to reject claims 27-29 and 33-34. The Office Action indicated on page 4 that the antimicrobial activity recited in claim 27 was not described in the references, but took the position that the properties set forth in claim 27 relating to antimicrobial activity were presumed to be present in the product that would result from combining Modak, Dresdner, McDevitt and Schichman. The September 2, 2011 Office Action further indicated that Applicants have the burden of demonstrating that the presently-claimed invention provides unexpected results.

11. The testing described in this Declaration was conducted in order to demonstrate whether the combination of the teachings of Modak, Dresdner, McDevitt and Schichman results in a packaged elastomeric article that exhibits the claimed antimicrobial properties.

12. A copy of the test protocol and results achieved are provided in Exhibit B. The test results were subjected to statistical analysis in Exhibit C, and a graphical interpretation of that statistical analysis is presented in Exhibit D.

13. Based on the test results set forth in Exhibits B-D, the combination of the teachings of Modak, Dresdner, McDevitt and Schichman does not result in a packaged antimicrobial elastomeric article that exhibits the property wherein the packaged elastomeric article is capable of causing at least 1 $\log_{10}$ reduction of the initial number of microorganisms that come into contact with the treated glove surface in five minutes of contact after being stored and/or transported for at least 45 days.

14. All statements made herein of my own knowledge are true; all statements made herein on information and belief are believed to be true; and I acknowledge that any willful false statements and the like made herein are punishable by fine or imprisonment, or both under 18 U.S.C. §1001 and may jeopardize the validity of the application or any patent issuing therefrom.

Nicholas R. Krogman

Nicholas R. Krogman, Ph.D.

9/29/21

Date

Exhibits:
- A – Curriculum Vitae of Nicholas R. Krogman, Ph.D.
- B – Test Protocol and Results
- C – Statistical Analysis of Results
- D – Figures for Statistical Analysis of Test Results

EXHIBIT A

Nicholas R. Krogman

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Highlights

- Extensive experience in synthetic polymer chemistry
- Experience with chemical formulation
- Hands on knowledge with multiple chemical and physical characterization techniques
- Pilot-scale chemical synthesis and plant process optimization experience
- Design of Experiment and statistical analysis education and experience
- Technical team leader in charge of delivering goals and organizing data to meet project timelines

Experience

1) February 2010-Present: Senior Research Scientist-Cardinal Health, R&D
   Technical lead tasked with the developing new products to fit the portfolio for the Patient Care Business unit. New products are guided through using the Stage/Gate process that requires my leadership to guide the technical team to meet specific goals to meet project deadlines.
   - Responsible for technical decisions and direction for the development of various medical products
   - Delivered new products and protected with IP of innovative antimicrobial applications to medical devices
   - Experience working with Quality Assurance groups to deliver FDA device clearance
   - Innovated new uses of plasma surface treatment in the medical and industrial glove industry

2) August 2009-January 2010: Senior Scientist-Air Products and Chemicals, Inc.; Chemical R&D Process Technology
   Solved business critical problems and needs by leveraging chemistry skills and knowledge to solve production problems for commercial processes that utilize optimization, problem solving, and cost reduction skills with a focus on expediting the commercialization of new products with a team of engineers and scientists.
   - Optimization of the polyurethane binder/adhesive process to meet increased production needs
   - Delivered chemical process knowledge to transfer adhesion promoter from outside toller to in-house manufacturing plant
   - Develop process for scaling of novel polyimides to supply Air Products membrane business unit
   - Develop process chemistry/engineering skills and time management skills while engaging multiple projects

3) June 2008-August 2009: Senior Chemist-Air Products and Chemicals, Inc.; Global Technology Center
   Implemented new chemistries and created innovative options surrounding crosslinked functional polyimides with a team of scientists and engineers to develop/scale-up a crosslinkable polyimide for fabrication into hollow fiber gas separation membrane units. Lead the polymer development surrounding thermal rearrangement of polyimides.
   - Delivered intellectual property surrounding polyimide synthesis
   - Integration of new chemistry and material treatment options to crosslink polyimide membranes
   - Developed/optimized lab-scale synthesis and transferred process to pilot-scale
   - Team lead for the development of next generation polymer development

4) August 2003-May 2008: Graduate Assistant, The Pennsylvania State University
Lead collaborative research efforts for the development of polyphosphazenes as biomaterials for uses that include tissue replacement, drug delivery vehicles, and stem cell growth substrates. Responsible for the design/development of novel bioerodible polyphosphazenes and the evaluation of polymer blend response with organic bioerodible polymers.
   - Modeled hydrolytic degradation studies
   - Materials fabrication including film casting and electrostatic spinning
   - Supervision of 3 graduate students and 2 undergraduate students
   - Collaborative projects with four different research groups on four different projects

Education

- Ph.D., Polymer Chemistry-August 2008
  The Pennsylvania State University, State College, PA: GPA-3.3
  Thesis Title: "Polyphosphazenes for Advanced Biomaterial Applications"
- B.S., Chemistry, Mathematics minor-May 2003
  University of Wisconsin-La Crosse, La Crosse, WI

Publications

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- Deng, M.; Nair, L.S.; Nukavarapu, S.G.; Brown, J.L.; Krogman, N.R.; Allcock, H.R.; Laurencin, C.T. "Biomimetic, Bioactive Etheric Polyphosphazene-Poly(lactide-co-glycolide) Blends for Bone Tissue Engineering." Journal of Biomedical Materials Research (2010), 92A(1), 114-125.
- Sethuraman, S.; Nair, L.S.; El-Amin, S.; Nguyen, M.T.; Singh, A.; Krogman, N.R.; Greish, Y.E.; Allcock, H.R.; Brown, P.W.; Laurencin, C.T. "Mechanical Properties and Osteocompatibility of Novel Biodegradable Alanine-Based Polyphosphazenes: Side Group Effects." Acta Biomaterials (2010), 6, 1931-1937.
- Deng, M.; Nair, L.S.; Nukavarapu, S.P.; Jiang, T.; Kanner, W.A.; Xudong, L.; Kumbar, S.G.; Weikel, A.L.; Krogman, N.R.; Allcock, H.R.; Laurencin, C.T. "Dipeptide-Based Polyphosphazene and Polyester Blends for Bone Tissue Engineering." Biomaterials (2010), 31(18), 4898-4908.
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- Weikel, A.L.; Krogman, N.R.; Nguyen, N.Q.; Nair, L.S.; Laurencin, C.T.; Allcock, H.R. "Polyphosphazenes that Contain Dipeptide Side Groups: Synthesis, Characterization, and Sensitivity to Hydrolysis." Macromolecules (2009), 42(3) 636-639.
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Presentations

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- Polyphosphazene Bioerodible Polymers for Bone Tissue Engineering; Allcock, H.R.*, Krogman, N.R., Singh, A., Laurencin, C.T. The 41st IUPAC World Chemistry Congress: Turin, Italy; August 2007.
- Polymers for Biological Applications; Krogman, N.R. *, Allcock, H.R., Materials Symposium: University Park, PA; April 2007.
- Poly(organophosphazenes) for Hard Tissue Repair and Replacement; Krogman, N.R. *, Allcock, H.R. Crossover Conference-Pennsylvania State University: University Park, PA; October 2006.

- Synthesis, Characterization, and In-Vitro Degradation of L-Alanine Co-Substituted Polyphosphazenes; Singh, A.*, Krogman, N.R., Sethuraman, S., Nair, L.S., Sturgeon, J.L., Brown, P.W., Laurencin, C.T., Allcock, H.R. 230th ACS National Meeting: Washington D.C.; August 2005.
- In-Vivo Biocompatibility Evaluation of Novel Amino Acid Ester Based Biodegradable Polyphosphazenes for Biomedical Applications; Sethuraman, S.*, Nguyen, T., Nair, L.S., Singh, A., Krogman, N.R., Allcock, H.R., Greish, Y., Brown, P.W., Laurencin, C.T. Proceedings of the Society for Biomaterials Conference: Memphis, TN; April 2005.
- Design of High Strength Degradable Polyphosphazenes: Modulation of Mechanical Properties Via Side Chain Chemistry; Sethuraman, S.*, Nguyen, T., Nair, L.S., Singh, A., Krogman, N.R., Allcock, H.R., Greish, Y., Brown, P.W., Laurencin, C.T. Symposium on Mechanical Properties of Bio-Inspired and Biological Materials-MRS Fall Meeting: Boston, MA; November 2004.
- Poly(organophosphazenes) for Hard Tissue Repair and Replacement; Singh, A.*, Krogman, N.R., Allcock, H.R. Crossover Conference-Pennsylvania State University: University Park, PA; October 2004.

**Denotes Presenter*

Affiliations

- American Chemical Society, 2005-present
- Materials Research Society, 2007-present

EXHIBIT B

Test Protocol for Antimicrobial-Coated Elastomeric Articles

1.0 Materials

Rollprint ClearFoil® film, RPP# 37-4219
Rollprint Triad "C" film, RPP# 36-1269
Amcor aluminum foil film, RFE-011
Natural rubber latex, Polyone
Surfynol DF-37, Air Products
Calcium nitrate, Sigma Aldrich
Calcium carbonate, Sigma Aldrich
Hydroxyethyl cellulose, Spectrum
Surfynol TG, Air Products
LE-46, Momentive
Chlorhexidine gluconate, Xttrium
Bardac 2250, Lonza
Trisorb Desiccant

2.0 Procedure

2.1 Natural Rubber Latex Film Preparation

Latex films were fabricated as follows:

Dip plates were cleaned with 1% aqueous hydrochloric acid, followed by 0.06% aqueous ammonium hydroxide, and finally dried at 100°C for 20 minutes.

The natural rubber latex dipping solution was prepared by adding 2000 mL of 60% concentrate natural rubber latex to 1600 mL of deionized water with 1.7 mL of Surfynol DF-37. The pH was adjusted to 10.0 using ammonium hydroxide. The latex solution was mixed using a magnetic stir bar for 10 minutes, then left to stand for 20 minutes. This solution was gently stirred before the films were formed.

The coagulant was fabricated by mixing 140.0 g of calcium nitrate and 140.0 g of calcium carbonate with 1.0 mL of Surfynol TG and 4000 mL of deionized water. This solution was heated to 50°C before dipping began.

The clean, dry dip plates were submerged into the coagulant at 50°C for 24 seconds, and then dried at 100°C for 75 seconds. The powdered dip plates were then dipped into the coagulant for 15 seconds, then dried at 100°C for 5 minutes. The natural rubber latex coated plates were then dipped into a water bath at 65°C for 3 minutes. Finally, the films were hung and dried at room temperature.

2.2 Antimicrobial Coating of Natural Rubber Latex Films

The antimicrobial coating consisted of 20.0g of hydroxyethyl cellulose, 10.0g of LE-46, 4.0g of Bardac 2250, 50.0g of CHG (20% solids in water), and mixed with deionized water up to 4000 mL. This solution was stirred for 20 minutes before coating occurred.

The dry natural rubber latex films were dipped into the antimicrobial solution for 10 seconds, and then dried at 100°C for 60 minutes.

2.3 Packaging of Antimicrobial Natural Rubber Latex Films

Three different packaging prototypes were fabricated and consisted of the following materials:

1. ClearFoil® with Triad "C" (Package 1, Table 1)
2. Triad "C" (Package A, Table 1)
3. Amcor aluminum foil (Package I, Table 1)

Antimicrobial coated natural rubber latex films were placed into the packages with Trisorb desiccant and the package was hermetically sealed using a heat sealer. These packages were then placed into an oven at 70°C for 45 days.

2.4 Antimicrobial Efficacy Analysis

Antimicrobial efficacy was conducted as outlined in U.S. Patent Application No. 10/783,362 against MRSA, *E. coli*, and *P. aeruginosa*. MRSA and *E. coli* were tested for fresh efficacy (fresh means before conditioning at 70°C for 45 days), and MRSA, *E. coli*, and *P. aeruginosa* were tested after the samples were conditioned at 70°C for 45 days. 5 minute contact time was tested with all organisms.

3.0 Results

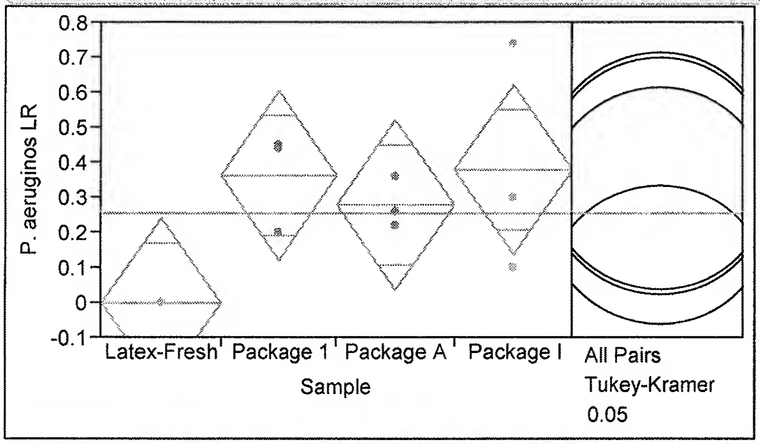
The final microbial results are shown below in Table 1:

P. aeruginosa LR	*E. coli* LR	MRSA LR	Conditioning	Replicate	Sample
0	1.99	1.26	Fresh	1	Latex-Fresh
0	1.92	1.25	Fresh	2	Latex-Fresh
0	3.56	1.75	Fresh	3	Latex-Fresh
0.44	0.04	0.3	45 days @ 70 C	1	Package 1
0.45	0.06	0.36	45 days @ 70 C	2	Package 1
0.2	0.93	0.38	45 days @ 70 C	3	Package 1
0.26	0	0.62	45 days @ 70 C	1	Package A
0.36	0	0.45	45 days @ 70 C	2	Package A
0.22	0	0.54	45 days @ 70 C	3	Package A
0.1	0	0.61	45 days @ 70 C	1	Package I
0.3	0	0.74	45 days @ 70 C	2	Package I
0.74	0	0.94	45 days @ 70 C	3	Package I

Table 1: Antimicrobial efficacy results of the antimicrobial coated natural rubber latex films before and after conditioning. LR stands for log reduction. "Fresh" conditioning references samples that were tested immediately following fabrication.

EXHIBIT C

Oneway Analysis of P. aeruginos LR By Sample



Oneway Anova

Summary of Fit

Rsquare	0.513016
Adj Rsquare	0.330397
Root Mean Square Error	0.181957
Mean of Response	0.255833
Observations (or Sum Wgts)	12

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Sample	3	0.27902500	0.093008	2.8092	0.1079
Error	8	0.26486667	0.033108		
C. Total	11	0.54389167			

Means for Oneway Anova

Level	Number	Mean	Std Error	Lower 95%	Upper 95%
Latex-Fresh	3	0.000000	0.10505	-0.2423	0.24225
Package 1	3	0.363333	0.10505	0.1211	0.60559
Package A	3	0.280000	0.10505	0.0377	0.52225
Package I	3	0.380000	0.10505	0.1377	0.62225

Std Error uses a pooled estimate of error variance

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

q*	Alpha
3.20234	0.05

Abs(Dif)-HSD

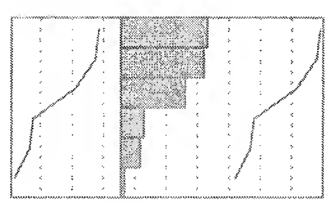
	Package I	Package 1	Package A	Latex-Fresh
Package I	-0.47576	-0.45910	-0.37576	-0.09576
Package 1	-0.45910	-0.47576	-0.39243	-0.11243
Package A	-0.37576	-0.39243	-0.47576	-0.19576
Latex-Fresh	-0.09576	-0.11243	-0.19576	-0.47576

Positive values show pairs of means that are significantly different.

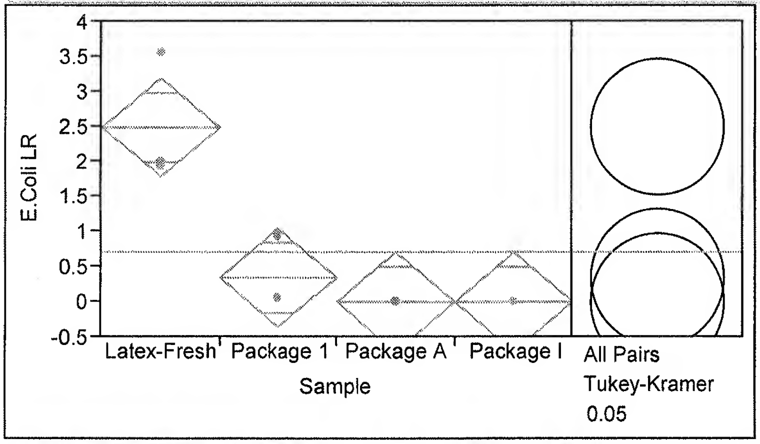
Level		Mean
Package I	A	0.38000000
Package 1	A	0.36333333
Package A	A	0.28000000
Latex-Fresh	A	0.00000000

Levels not connected by same letter are significantly different.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Package I	Latex-Fresh	0.3800000	0.1485672	-0.095763	0.8557634	0.1240
Package 1	Latex-Fresh	0.3633333	0.1485672	-0.112430	0.8390967	0.1450
Package A	Latex-Fresh	0.2800000	0.1485672	-0.195763	0.7557634	0.3059
Package I	Package A	0.1000000	0.1485672	-0.375763	0.5757634	0.9044
Package 1	Package A	0.0833333	0.1485672	-0.392430	0.5590967	0.9409
Package I	Package 1	0.0166667	0.1485672	-0.459097	0.4924301	0.9995



Oneway Analysis of E.Coli LR By Sample



Oneway Anova

Summary of Fit

Rsquare	0.85258
Adj Rsquare	0.797298
Root Mean Square Error	0.528709
Mean of Response	0.708333
Observations (or Sum Wgts)	12

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Sample	3	12.933100	4.31103	15.4223	0.0011*
Error	8	2.236267	0.27953		
C. Total	11	15.169367			

Means for Oneway Anova

Level	Number	Mean	Std Error	Lower 95%	Upper 95%
Latex-Fresh	3	2.49000	0.30525	1.786	3.1939
Package 1	3	0.34333	0.30525	-0.361	1.0472
Package A	3	0.00000	0.30525	-0.704	0.7039
Package I	3	0.00000	0.30525	-0.704	0.7039

Std Error uses a pooled estimate of error variance

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

q*	Alpha
3.20234	0.05

Abs(Dif)-HSD

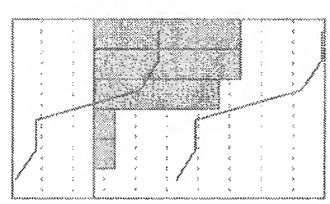
	Latex-Fresh	Package 1	Package A	Package I
Latex-Fresh	-1.3824	0.7642	1.1076	1.1076
Package 1	0.7642	-1.3824	-1.0391	-1.0391
Package A	1.1076	-1.0391	-1.3824	-1.3824
Package I	1.1076	-1.0391	-1.3824	-1.3824

Positive values show pairs of means that are significantly different.

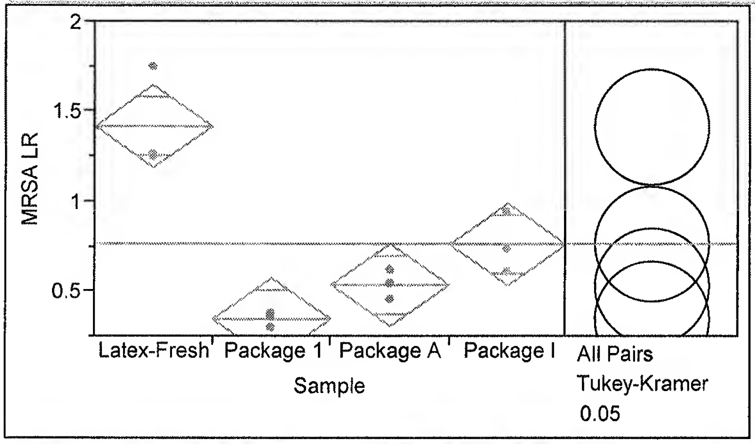
Level		Mean
Latex-Fresh	A	2.4900000
Package 1	B	0.3433333
Package A	B	0.0000000
Package I	B	0.0000000

Levels not connected by same letter are significantly different.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Latex-Fresh	Package A	2.490000	0.4316892	1.10758	3.872417	0.0019*
Latex-Fresh	Package I	2.490000	0.4316892	1.10758	3.872417	0.0019*
Latex-Fresh	Package 1	2.146667	0.4316892	0.76425	3.529084	0.0048*
Package 1	Package A	0.343333	0.4316892	-1.03908	1.725751	0.8547
Package 1	Package I	0.343333	0.4316892	-1.03908	1.725751	0.8547
Package I	Package A	0.000000	0.4316892	-1.38242	1.382417	1.0000



Oneway Analysis of MRSA LR By Sample



Oneway Anova

Summary of Fit

Rsquare	0.892702
Adj Rsquare	0.852465
Root Mean Square Error	0.171974
Mean of Response	0.766667
Observations (or Sum Wgts)	12

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Sample	3	1.9684667	0.656156	22.1862	0.0003*
Error	8	0.2366000	0.029575		
C. Total	11	2.2050667			

Means for Oneway Anova

Level	Number	Mean	Std Error	Lower 95%	Upper 95%
Latex-Fresh	3	1.42000	0.09929	1.1910	1.6490
Package 1	3	0.34667	0.09929	0.1177	0.5756
Package A	3	0.53667	0.09929	0.3077	0.7656
Package I	3	0.76333	0.09929	0.5344	0.9923

Std Error uses a pooled estimate of error variance

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

q*	Alpha
3.20234	0.05

Abs(Dif)-HSD

	Latex-Fresh	Package I	Package A	Package 1
Latex-Fresh	-0.44966	0.20701	0.43367	0.62367
Package I	0.20701	-0.44966	-0.22299	-0.03299
Package A	0.43367	-0.22299	-0.44966	-0.25966
Package 1	0.62367	-0.03299	-0.25966	-0.44966

Positive values show pairs of means that are significantly different.

Level		Mean
Latex-Fresh	A	1.4200000
Package I	B	0.7633333
Package A	B	0.5366667
Package 1	B	0.3466667

Levels not connected by same letter are significantly different.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Latex-Fresh	Package 1	1.073333	0.1404160	0.623673	1.522994	0.0003*
Latex-Fresh	Package A	0.883333	0.1404160	0.433673	1.332994	0.0011*
Latex-Fresh	Package I	0.656667	0.1404160	0.207006	1.106327	0.0069*
Package I	Package 1	0.416667	0.1404160	-0.032994	0.866327	0.0697
Package I	Package A	0.226667	0.1404160	-0.222994	0.676327	0.4230
Package A	Package 1	0.190000	0.1404160	-0.259661	0.639661	0.5584

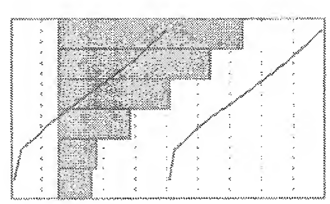
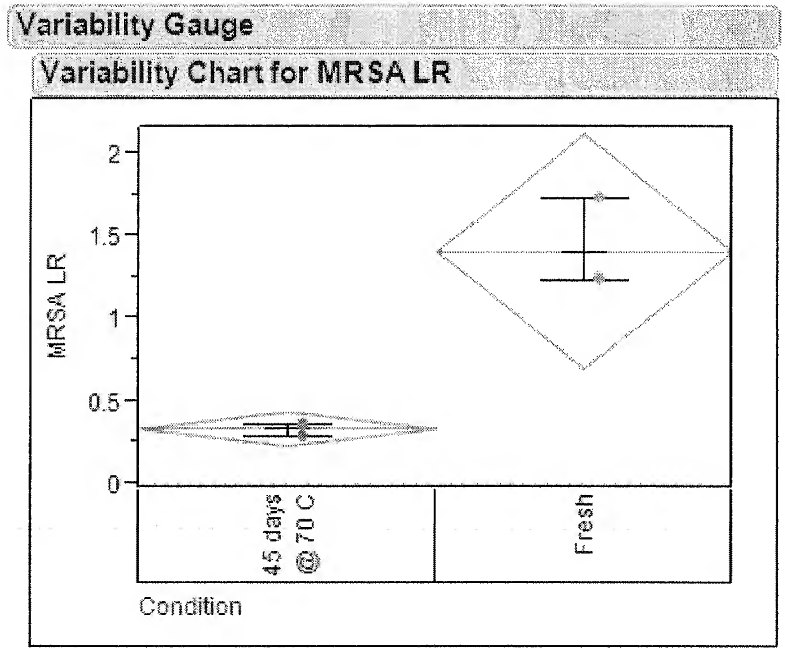
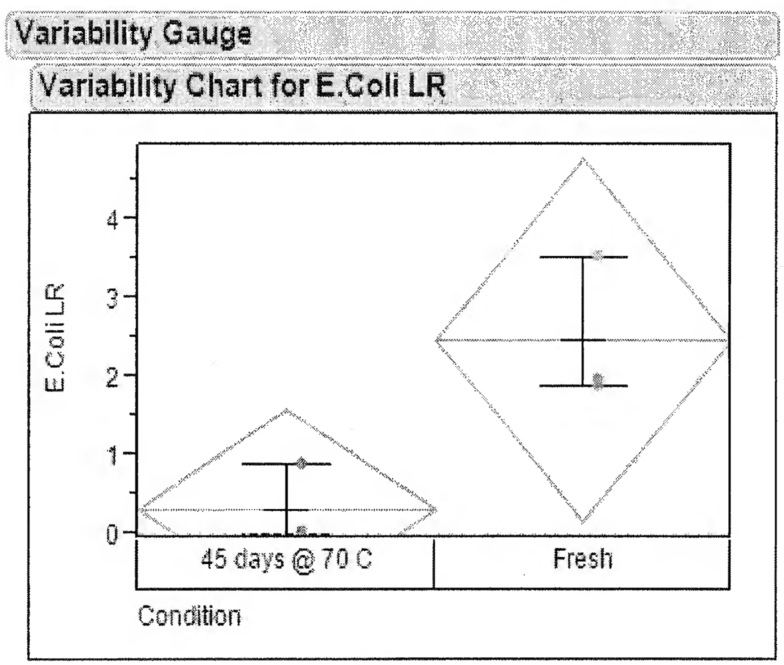


EXHIBIT D



Variability Gauge
Variability Chart for MRSA LR
MRSA LR
2
1.5
1
0.5
0
45 days @ 70 C
Fresh
Condition



Variability Gauge
Variability Chart for E.Coli LR
E.Coli LR
4
3
2
1
0
45 days @ 70 C
Fresh
Condition